

U.S. Serial No.: 10/665,708
Filed: September 18, 2003
(RCE filed June 7, 2007)

SUPPLEMENTARY AMENDMENT

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Please amend claims 1, 3, 4, 13, and 16-18 as shown below.

1. (Withdrawn - Currently Amended) A method of detecting *Mycobacterium* species present in a biological sample, comprising the steps of:

providing a biological sample containing nucleic acid from at least one *Mycobacterium* species comprising a *Mycobacterium* 16S ribosomal RNA (rRNA) or DNA encoding a *Mycobacterium* 16S rRNA;

amplifying the *Mycobacterium* 16S rRNA or *Mycobacterium* DNA encoding the *Mycobacterium* 16S rRNA in an *in vitro* nucleic acid amplification mixture comprising at least one polymerase activity, and a combination of at least one first oligonucleotide and at least one second oligonucleotide, wherein the first oligonucleotide consists of a ~~promoter sequence and a target-specific sequence that hybridizes to a~~ *Mycobacterium* 16S rRNA or DNA sequence ~~consists of SEQ ID NO:5 that is joined to a 5' promoter sequence~~, and the second oligonucleotide is an oligonucleotide consisting of 19 to 25 bases made up of contiguous bases 1 to 18 of SEQ ID NO:24 and optionally three to seven bases 5' to the contiguous bases 1 to 18 of SEQ ID NO:24 and/or optionally one base 3' to the contiguous bases 1 to 18 of SEQ ID NO:24 to produce amplified *Mycobacterium* nucleic acid; and

detecting the amplified *Mycobacterium* nucleic acid by detecting a label associated with the amplified *Mycobacterium* nucleic acid.

2. (Withdrawn - Original) The method of Claim 1, further comprising in the steps of:

adding to the biological sample at least one capture oligonucleotide that specifically hybridizes to the *Mycobacterium* 16S rRNA and an immobilized nucleic acid that hybridizes to the capture oligonucleotide under hybridizing conditions to produce a hybridization complex; and

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separating the hybridization complex from other components of the biological sample before the amplifying step.

3. (Withdrawn - Currently Amended) The method of Claim 1, wherein the amplifying step amplifies 16S rRNA or DNA encoding 16S rRNA from *M. tuberculosis* or a *Mycobacterium* other than *tuberculosis* (MOTT) species.

4. (Withdrawn - Currently Amended) The method of Claim 1, wherein the amplifying step amplifies 16S rRNA or DNA encoding 16S rRNA from *M. abscessus*, *M. africanum*, *M. asiaticum*, *M. avium*, *M. bovis*, *M. celatum*, *M. chelonae*, *M. flaveoceans*, *M. fortuitum*, *M. gastri*, *M. gordoniæ*, *M. haemophilum*, *M. intracellulare*, *M. interjectum*, *M. intermedium*, *M. kansasii*, *M. malmoense*, *M. marinum*, *M. non-chromogenicum*, *M. paratuberculosis*, *M. phlei*, *M. scrofulaceum*, *M. shimoidei*, *M. simiae*, *M. smegmatis*, *M. szulgai*, *M. terrae*, *M. triviale*, *M. tuberculosis*, *M. ulcerans* or *M. xenopi*.

5. (Withdrawn - Original) The method of Claim 1, wherein the detecting step uses at least one probe that hybridizes specifically to the amplified *Mycobacterium* nucleic acid.

6. (Withdrawn - Original) The method of Claim 5, wherein the detecting step uses at least one labeled probe that hybridizes specifically to the amplified *Mycobacterium* nucleic acid.

7. (Withdrawn - Original) The method of Claim 5, wherein the detecting step uses a plurality of probes that hybridize specifically to the amplified *Mycobacterium* nucleic acid.

8. (Withdrawn - Previously amended) The method of Claim 1, wherein the amplifying

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step uses a combination of at least a first primer and a second primer, wherein the first primer consists of SEQ ID NO:11, and the second primer is selected from the group consisting of SEQ ID NO:21, SEQ NO:22, SEQ ID NO:23 and SEQ ID NO:24.

9. (Withdrawn - Previously amended) The method of Claim 8, wherein the second primer consists of SEQ ID NO:21.

10. (Withdrawn - Previously amended) The method of Claim 8, wherein the second primer consists of SEQ ID NO:22.

11. (Withdrawn - Previously amended) The method of Claim 8, wherein the second primer consists of SEQ ID NO:23.

12. (Withdrawn - Previously amended) The method of Claim 8, wherein the second primer consists of SEQ ID NO:24.

13. (Currently Amended) A composition for amplifying in an in vitro amplification reaction a *Mycobacterium* 16S rRNA sequence or a DNA encoding 16S rRNA, comprising a combination of at least one first oligonucleotide and at least one second oligonucleotide, wherein the first oligonucleotide consists of a promoter sequence and a target-specific sequence that hybridizes to a *Mycobacterium* 16S rRNA or DNA sequence consists of SEQ ID NO:5 that is joined to a 5' promoter sequence, and wherein the second oligonucleotide is an oligonucleotide consisting of 19 to 25 bases made up of contiguous bases 1 to 18 of SEQ ID NO:24 and optionally three to seven bases 5' to the contiguous bases 1 to 18 of SEQ ID NO:24 and/or optionally one base 3' to the contiguous bases 1 to 18 of SEQ ID NO:24.

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14. (Previously amended) The composition of Claim 13, wherein the composition comprises:

at least one first oligonucleotide consisting of SEQ ID NO:11, and

at least one second oligonucleotide consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23 or SEQ ID NO:24.

15. (Previously amended) The composition of Claim 14, wherein the composition comprises:

the at least one first oligonucleotide consisting of SEQ ID NO:11, and

the at least one second oligonucleotide consisting of SEQ ID NO:21.

16. (Currently Amended) A kit containing ~~one or more oligonucleotides, wherein said one or more oligonucleotides consist~~ at least a pair of oligonucleotides, wherein at least one first oligonucleotide consists of a target-specific sequence that consists of SEQ ID NO:5 that is joined to a 5' promoter sequence, and wherein at least one second oligonucleotide consists of a sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:24.

17. (Currently Amended) The kit of claim 16, further containing an oligonucleotide consisting wherein the first oligonucleotide consists of SEQ ID NO:11.

18. (Currently Amended) The kit of claim 17, containing wherein:

[[a]] the first oligonucleotide consisting consists of SEQ ID NO:11, and

the at least one second oligonucleotide consisting consists of SEQ ID NO:21,

SEQ ID NO:22, or SEQ ID NO:23.

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19. (Previously amended) The composition of Claim 14, wherein the composition comprises:

the at least one first oligonucleotide consisting of SEQ ID NO:11, and
the at least one second oligonucleotide consisting of SEQ ID NO:23.

20. (Previously amended) The composition of Claim 14, wherein the composition comprises:

the at least one first oligonucleotide consisting of SEQ ID NO:11, and
the at least one second oligonucleotide consisting of SEQ ID NO:24.